UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., Plaintiff,	:	
against-	:	**07 Civ. 7343 (HB)**
	:	**OPINION & ORDER**
SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC and AVENTIS PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Hon. HAROLD BAER, JR., District Judge:

I. BACKGROUND

Louisiana-Wholesale Drug Company ("Louisiana Wholesale" or "Plaintiff") filed a complaint on August 17, 2007 alleging that Aventis Pharmaceuticals, Inc. ("Aventis"), Sanofi-Aventis, and Sanofi-Aventi U.S., LLC ("Defendants") violated antitrust law under Section 2 of the Sherman Act, 15 U.S.C. § 2 when it filed a sham Citizen-Petition to the Federal Drug Administration ("FDA") to block the approval of five generic manufacturers' Abbreviated New Drug Applications ("ANDA") to produce a generic version of Aventis' rheumatoid-arthritis drug leflunomide, called Arava. Louisiana Wholesale claims that Aventis filed the Petition to willfully maintain and extend its monopoly power over the drug and be able to continue to charge supra-competitive prices to direct purchasers like the Plaintiff and the public at large. Defendants move to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6) on three grounds.

First, Defendants argue that the Citizen-Petition was not a sham, but legitimate petitioning activity pursuant to FDA regulations under the Noerr-Pennington doctrine, which provides First Amendment-based immunity from antitrust liability. Defendants argue that even if the sham exception to Noerr-Pennington immunity applied, the Plaintiff has failed to prove that the Petition was "objectively baseless," a required hurdle in deciding to strip it of its First Amendment protection. Second, Defendants allege that the Plaintiff lacks antitrust standing to sue Sanofi-Aventis for two reasons. Defendants state that the Plaintiff failed to allege any facts to support its allegation that Defendants actually delayed FDA approval of the generic drugs. Defendants also argue that the most "efficient enforcers" of antitrust claims here are the generic

manufacturers, not Louisiana Wholesale. Finally, Defendants argue that the Plaintiff has failed to allege a "relevant market" as required by Section 2 of the Sherman Act.

For the reasons set forth below, I deny the Defendants' motion to dismiss the complaint on all three grounds.

A. Facts

Plaintiff alleges that Defendants used willful and exclusionary means as part of a scheme to improperly maintain and extend their monopoly in the leflunomide market. Compl. ¶ 82. Specifically, Plaintiff alleges that Defendants' scheme was to delay or minimize the entry of generic leflunomide competitors into the market, which would have permitted sale of the generic drug in the United States at prices significantly below Defendants' prices for Arava, the brand version of leflunomide. Compl. ¶ 83. Defendant Aventis acquired the exclusive right to market Arava in 10-milligram (mg), 20-mg and 100mg strengths for five years and six months on September 10, 1998. See Compl. Exh. 1, at 3. The 100mg strength served as a loading dose to be taken for three days to "quickly reach steady state plasma concentrations" of the metabolized form of leflunomide. See Compl., Exh. 1, at 2. Aventis stopped selling the 100-mg tablet in pharmacies in January 2002, but continued distribution at no charge to physicians via blister packs of three tablets for the loading dose. See Compl. Exh. 1, at 1, 3. Five generic manufacturers submitted Abbreviated New Drug Applications ("ANDAs") seeking permission to market and sell AB-rated generic leflunomide[1] on March 10, 2004, the exact date of expiration of Aventis' exclusive marketing period. See Compl. ¶51; Compl. Exh. 1, at 3, n.6.

Plaintiff alleges that Aventis filed an "objectively baseless (i.e. sham) Citizen Petition" to delay FDA final approval of these ANDAs. Compl. ¶¶ 5-6. Pursuant to FDA regulation 21 C.F.R. 10.30, any person may file a Citizen Petitions with the FDA to request that the FDA take, or refrain from taking, administrative action, including approving or denying ANDAs, based on genuine safety, scientific or legal concerns . See Compl. ¶35. Plaintiff alleges that Aventis filed the Petition on March 31, 2005 "on the eve" of final approval, one year after the generic manufacturers submitted their ANDAs to the FDA for approval. See Compl. ¶ 51; see also

[1] AB-rated generic versions of brand name drugs contain the same active ingredient because they are determined to be "bioequivalent" to the brand name drug counterparts, providing the same amount of active ingredient in a patient's bloodstream for the same amount of time. Compl. ¶ 3. AB-rated generics enable direct purchasers to purchase generic versions of brand name drugs at substantially lower prices without seeking or obtaining permission from the prescribing doctor, unless the prescription is denominated "Dispense as Written"). See Compl. ¶¶ 33-34

Compl. Exh. 1, at 3, n.6. Plaintiff alleges that Aventis knew that filing the petition would delay FDA approval pursuant to FDA practice, which considers and rules on Citizen Petitions prior to granting final approval to ANDAs. See Compl. ¶ 51; Compl. Exh. 1, at 3, n.6. On September 13, 2005, six months later, the FDA responded that Aventis's "Petition is denied. . . . based on a review of the Petition and the comments submitted in response to it, as well as other information available to the Agency." See Compl. Exh. 1 at 1.

Plaintiff filed its Complaint on August 17, 2007 alleging violations of the Section 2 the Sherman Antitrust Act, 15 U.S.C. §2 and requesting treble damages, which are authorized for anticompetitive injuries under §4 of the Clayton Act, 15 U.S.C. §15. The complaint was supplemented by two accompanying Exhibits: (1) the letter from Dr. Steven K. Galson Director of the Center for Drug Evaluation and Research, Department of Health & Human Services, to Aventis Pharmaceuticals, Inc. denying the latter's Citizen Petition dated September 13, 2005 and (2) the Citizen Petition filed by Aventis Pharmaceuticals Inc.'s Citizen Petition filed pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §355(j)), 21 C.F.R. 314.94(a)(7) and 21 C.F.R. part 320 dated March 31, 2005. Defendants moved to dismiss the complaint under Rule 12(b)(6) of the F.R.C.P. on October 15, 2007. A hearing on the motion was held on January 4, 2008.

B. Legal Standard Governing Motions to Dismiss

A complaint should be dismissed if it "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Historically, courts have cautioned that motions to dismiss in antitrust cases should be granted "very sparingly" and that "the plaintiff should be given ample opportunity for discovery." See Am. Med. Assoc. v. United Healthcare Corp., No. 00-Civ-2800, 2007 WL 683974 (S.D.N.Y. March 5, 2007) (quoting Hosp. Blg. Co. v. trs. Of Rex Hosp., 425 U.S. 738, 746 (1976)); see also, e.g., Dickson v. Microsoft Corp., 309 F.3d 193, 212 (4th Cir. 2002). While detailed factual allegations are not needed, they must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true to survive a Rule 12(b)(6) motion to dismiss. Bell v. Twombly, 127 S. Ct. 1955, 1964 (2007).

"In deciding the motion, the Court may consider documents referenced in the Complaints and documents that are in the relevant antitrust plaintiffs' possession or that they knew of and relied

on in bringing suit [and t]he "Court may also consider 'matters of which judicial notice may be taken.'" In re Buspirone Patent Litigation, 185 F. Supp. 2d 363, 367 (S.D.N.Y. 2002) (internal citing references omitted). Id. (internal citing references omitted).

II. DISCUSSION

Section 2 Claims under the Sherman Antitrust Act – 15 U.S.C. §2

The Sherman Antitrust Act prohibits the formation of monopolies over trade or commerce. 15 U.S.C §2. To establish a monopolization claim under §2 of the Sherman Act, a claimant must prove that defendant possesses monopoly power in a relevant market, and in addition, must show that the defendant has exercised willful acquisition or maintenance of that power as distinguished from growth or development as consequence of superior product, business acumen, or historic accident. See Verizon Comm'ns Inc. v. Law Officers of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); See Geneva Pharmaceuticals Tech. Corp. v. Barr Laboratories, Inc., 386 F.3d 485 (2d Cir. 2004); Doron Precision Systems, Inc. v. FAAC, Inc., 423 F. Supp. 2d 173 (S.D.N.Y. 2006). "To recover, a plaintiff must show, inter alia, that it suffered an 'antitrust injury.' An antitrust injury is an injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. Paycom Billing Services, Inc. v. Mastercard Int'l Inc., 467 F.3d 283 (2d Cir. 2006) citing Brunswick Corp. V. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977); see also Blue Shield of Virginia v. McCready, 457 U.S. 465, 482-82 (1982) ("an increase of price resulting from a dampening of competitive market forces is assuredly one type of injury for which §4 potentially offers redress"). The plaintiff must also provide sufficient facts to support a determination of monetary damages to compensate for the antitrust injury. See GAF Corp. v. Eastman Kodak Co., 519 F. Supp. 1203 (S.D.N.Y. 1981).

A. Sham Exception to Noerr-Pennington Immunity

Conduct that unfairly seeks to limit competition in the marketplace is the type of activity that the Sherman Act directs itself. See New York Jets, 2005 U.S. Dist. LEXIS 23763, at *14 citing Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993). However, conduct aimed at persuading the government of a position or expressing views and wishes concerning government decisions is classic petitioning activity protected by the First Amendment that

cannot be limited by the Sherman Act. See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 137-138 (1961) and United Mine Workers v. Pennington, 381 U.S. 657 (1965). Such petitioning activity is generally immune from suit under the Sherman Act even if it produces a restraint or a monopoly. See Noerr, 365 U.S. at 137; Pennington, 381 U.S. at 670. A valid attempt to procure government action, even when initiated to attain a competitive advantage, is protected by Noerr-Pennington. See City of Colum. v. Omni Outdoor Adver., Inc., 499 U.S. 365, 380-81 (1991).

But Noerr-Pennington immunity is not absolute; for instance, it does not protect the filing of "sham litigation." Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 516, 30 L. Ed. 2d 642, 92 S. Ct. 609 (1972). The Supreme Court defined a two-step inquiry into a sham filing claim. Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993):

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. . . . [Second,] a court should focus on whether the baseless suit conceals an attempt to interfere directly with a competitor's business relationships through the use of the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon. . . . [Thus, to disprove Noerr immunity, a plaintiff must] demonstrate both the objective and the subjective components of a sham.

Professional Real Estate Investors, 508 U.S. at 60-61. It is not the anticompetitive purpose alone which strips the petitioning activity of immunity, but in addition the fact that it is baseless. Id. at 58. Without a plaintiff's showing that a filing was objectively baseless, a court cannot look at the subjective intent of the defendant. See id. "The relevant issue is whether the legal challenges are brought pursuant to a policy of starting legal proceedings without regard for the merits [but rather] for the purpose of injuring a market rival." California Motor Transp., 404 U.S. at 512; PrimeTime 24 Joint Venture v. National Broadcasting Co., 219 F.3d 92, 101 (2d Cir. 2000) (holding that Plaintiffs did state a sham claim when they alleged that major television networks filed baseless, repetitive administrative signal strength challenges to overwhelm PrimeTime and make it difficult for it to comply with regulations).

"It is not what the parties think of the merits of their positions that matters; it is whether there are, in fact, sufficient objective bases for the positions taken." In re Buspirone Patent Litigation, 185 F. Supp. 2d at 375 (holding Bristol Myers Squibb's listing of its "365 Patent" in the "Orange Book" for patents and subsequent patent infringement litigations were objectively

baseless because the patent was no longer enforceable under a straightforward application of patent law). A meritless petition, submitted to impose undue delay and expense on a rival, will subject a defendant to antitrust liability. New York Jets, 2005 U.S. Distr. LEXIS 23763, at *21-22 (finding that the Jets stated a sham claim against Cablevision which funded support and promoted baseless litigation and presented a sham bid designed solely to delay, increase the cost of and prevent the development of the Sports and Convention Center project). Ignoring the law, filing administrative or legal actions that do not request reasonable extensions or development of the law, as well as mischaracterization of the relevant issues or legal standards exemplify objectively baseless actions. See Buspirone, 185 F. Supp. 2d at 376.

To constitute a "sham," Aventis's petition must have had no reasonable chance of success and must have been directed at harming the generic manufacturers' interests in some manner distinct from preventing any potential improper labeling of the generic leflunomide. See New York Jets, 2005 U.S. District LEXIS 23763, at *24; ICOS Vision System Corp., N.V. v. Scanner Tech. Corp., 2006 WL 838990 (S.D.N.Y. Mar. 29, 2006) ("If, as alleged, Scanner knew that §271(g) did not apply and threatened litigation for the sole purpose of harming ICOS, then its threats were neither objectively reasonable nor taken in good faith. This is all that need be alleged at this early stage of the litigation.") citing Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1354 (Fed. Cir. 1999) ("Obviously, if the patentee knows that the patent is invalid, enforceable, or not infringed, yet represents to the marketplace that a competitor is infringing the patent, a clear case of bad faith is made out.").

Louisiana Wholesale has alleged that the Defendants sought to block the approval of the generic ANDAs not because of the health concerns, but solely to delay and impede approval of generics so as to maintain its monopoly over the branded leflunomide market. See Compl. ¶¶ 47, 58, 66. It supports this allegation by arguing that Aventis, as a sophisticated pharmaceutical manufacturer familiar with FDA regulations and practices could have had no reasonable belief that its Citizen Petition was viable. See Compl. ¶¶ 58. Not only is this plausible, but Aventis in fact has been subject to those same regulations—the FDA itself pointed this out to Aventis in its denial of the Petition. See Compl. Exh. 1, at 6-7. The FDA specifically noted to Aventis that it had cross-referred to other brand drugs and strengths on its own generic and brand labels when

Aventis itself did not manufacture either the drug or the strength indicated. See Compl. Exh. 1, at 7.[2]

Drawing all inferences in favor of the Louisiana Wholesale as I must, it cannot be established that the Defendants are entitled to Noerr-Pennington immunity. The complaint and limited administrative record produced thus far demonstrates that there are triable issues of fact concerning the reasonability and viability of Aventis's Citizen Petition. Additional discovery may clarify the circumstances surrounding Aventis's filing of the petition one year after the generic manufacturers submitted their ANDAs for FDA approval when no new health and safety information on the loading dose or leflunomide in general and no new FDA regulations on labeling had occurred. If it becomes apparent that Aventis indeed sought to protect the public from deficient labeling and non-bioequivalent strengths of leflunomide, Defendants will likely be entitled to protection under Noerr-Pennington. However, if Louisiana Wholesale can establish that Aventis never intended or could reasonably expect to affect FDA labeling policy with respect to the five ANDAs, and filed the Petition solely to delay or impede the approval of

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[2] The FDA letter states in relevant part:

> Your argument seems to be based on a false premise, namely, that if a particular generic manufacturer recommends in leflunomide labeling a loading dose of 100 mg for three days (3 x 100 mg), the manufacturer either must (1) provide its own 100-mg product or (2) recommend using five of its 20-mg tablets. You incorrectly speculate that generic sponsors will attempt to either replace the 100-mg tablet loading dose from the label . . . . [Y]ou argue that replacing the 100-mg loading dose with a loading dose of five 20-mg tablets should require an in vivo bioequivalence study, and that it is legally and medically inappropriate to remove mention of the loading dose from the label. You seem to ignore a third possibility: that the labeling for a generic leflunomide product can recommend a loading dose of 3 x 100 mg that can be accomplished by the use of an approved 100-mg tablet from a different manufacturer. . . .
>
> As does the approved labeling for Arava . . . , approved labeling for generic leflunomide products would include the recommendation of using 100—mg tablets for the loading dose. . . . As reflected by existing precedents, ANDA sponsors may refer in their labeling to products they do not manufacture. . . . It is also not uncommon for brand name products to refer in their labeling to other drugs that are not provided by the sponsor of the brand name product (e.g., the labeling of Oncaspar, an Aventis product, recommends its use in combination with . . . products not made by Aventis . . .).
>
> Additionally, there is nothing in the Act or the regulations that requires an ANDA applicant to seek approval for all available strengths of the [reference listed drug]. . . .
>
> [Y]our concern that (1) this labeling will be omitted for generic leflunomide products that are approved at only 10-mg and 20-mg strengths, or (2) the labeling will be changed to recommend the use of five 20-mg tablets instead of a 100-mg tablet absent appropriate bioequivalence data, is unfounded.

Compl. Exh. 1, at 6-7.

generics, Noerr-Pennington immunity will be unavailable. Upon this record, Louisiana Wholesale's claim is entitled to proceed.

B. Antitrust Standing

A private plaintiff seeking relief under Section 2 of the Sherman Act must establish, as a threshold matter, that it has suffered "'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" Doron Precision Sys., Inc. v. FAAC, Inc., 423 F. Supp. 2d 173, 180 (S.D.N.Y. 2006) (internal citing references omitted). The plaintiff must plead specific facts showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market, not just on the plaintiff as a competitor. Doron, 423 F. Supp. 2d at 180 citing Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc., 996 F.2d 537, 543 (2d Cir. 1993).

It is beyond peradventure that the Plaintiff will be able to show a decrease in competition because the generic manufacturers were not able to produce the generic version of Arava until they received approval and prices could be maintained at the original level by Sanofi-Aventis. A valid antitrust injury would be an injury to the consumers whose power of choice was impaired as a result of Defendants' conduct. Doron, 423 F. Supp. 2d at 182. Conduct which destroys consumer choice meets the test and so it is here. The motion to dismiss on this ground must be denied.

Even if a plaintiff suffers antitrust injury, it may not be able to allege a claim if it does not have standing. See Paycom Billing Servs., Inc. v. Mastercard Int'l, 467 F.3d 283 (2d Cir. 2006). Citing to Paycom Billing Services, a Section 1, restraint of trade antitrust case, Defendants argue Louisiana is not the efficient enforcer of an alleged antitrust violation here and thus does not have standing to sue because it did not suffer direct harm, its injury is too speculative, it is not the entity whose self-interest would normally motivate it to vindicate the public interest in antitrust enforcement, and it is too difficult to identify damages and apportion them among direct and indirect victims to avoid duplicative recoveries. Def. Mot. to Dismiss, at 18-20.

The Plaintiff pleads enough at this stage to meet the requirements of the efficient enforcer. Louisiana alleges direct injuries by directly purchasing drugs from Sanofi-Aventis, and not merely experiencing a pass-on in costs; alleges identifiable damages (excess in the brand v. competitive price); has self-interest in pursuing the claim along with the generic manufacturers

were they to pursue the claim themselves; and alleges definite, not speculative injuries. Louisiana Wholesale was not indirectly injured, but directly as a purchaser. See, e.g., Bennett v. Cardinal Health Marmac Distributors, Inc., 2003 WL 21738604 (E.D.N.Y. 2003). (where principal shareholder of pharmacies that brought antitrust claims against wholesale suppliers of pharmaceuticals failed to sufficiently allege antitrust injury, as required to support claims under Sherman Act and Clayton Act; shareholder's harm was entirely derivative of harm allegedly suffered by pharmacies as result of their alleged refusal to supply products).

C. Relevant Market and Monopoly Power

In a §2 violation, plaintiffs must prove that defendants possessed monopoly power and willfully acquired or maintained that power in the relevant market; so, the first step is to define the relevant market. Geneva Pharm. Tech. Corp. v. Barr Laboraties, Inc., 396 F.3d 485, 495-96 (2d Cir. 2006). On a motion to dismiss, a plaintiff need only allege a "plausible" relevant market. New York Jets v. Cablevision Sys. Corp., No. 05CV2875, 2005 LEXIS 23763 (S.D.N.Y. Oct. 17, 2005). Relevant market is defined as all products reasonably interchangeable by consumers for the same purposes, since this constrains a firm's ability to raise prices above competitive levels. See Geneva, 386 F.3d at 496 citing United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956). After defining *the* relevant market, we turn to proof of monopoly power, which is defined as "the power to control prices or exclude competition." Geneva, 396 F.3d at 500 citing E.I. du Pont, 361 U.S. at 391.

Plaintiff alleges that the relevant market is the brand Arava (leflunomide) and its generic AB-rated equivalents, relying on Geneva, 386 F.3d 485 (2d Cir. 2004) (approving even a relevant market of just the generic versions); In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (finding that Cipro and its generics were the proper relevant market). Defendants argue that it should include leflunomide as well as a host of other anti-rheumatoid treatments available on the market. Because the Plaintiff has alleged a potentially viable market and issues of fact exist as to the appropriate circumscription of the relevant market, this issue cannot be decided now.

III. CONCLUSION

Defendants' Motion to Dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) is denied. The parties are directed to proceed with their motions on Class Certification under Fed. R. Civ. P. 23 and continue discovery pursuant to the Pre-Trial Scheduling Order dated December 3, 2007. I direct the Clerk of the Court to close this motion and remove it from my docket.

SO ORDERED
January 18, 2008
New York, New York

U.S.D.J.